REMARKS

In addition to the response filed October 14, 2008 Applicants submit the following remarks fully addressing all of the issues raised in the August, 13 2008 Final Office Action. Favorable reconsideration of the application in view of the following remarks is respectfully requested.

The Finality of the Rejection is Improper:

The Applicants filed a Request for Reconsideration on October 30, 2007. The Examiner issued a Non-Final Office Action dated January 23, 2008. Applicants submitted Response to the January 23, 2008 Non-Final Office Action containing no amendments to the claims. The final Office Action dated August 13, 2008 raises new grounds of rejection not recited in the previously issued Non-Final Office Action. "Under present practice, second or any subsequent actions on the merits shall be final, *except* where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement" (emphasis added). MPEP 706.07(a). The rejections relying on 35 U.S.C. § 112, first and second paragraphs, are new grounds of rejection not necessitated by an amendment of the claims. Therefore, it is requested that the finality of this rejection be withdrawn and that a new action be issued.

In order for this Response to be complete applicants submit the following remarks relating to the August 13, 2008 Office Action. Claims 1-4 and 6-9 are rejected. Claims 1 and 8-9 have been amended. Claims 1-4 and 6-9 are presently pending in the application. The basis for the amendment to claims 1 and 8-9 can be found in paragraph **[0025]** of the specification. Favorable reconsideration of the application in view of the following remarks is respectfully requested.

Rejection under 35 U.S.C. § 112, First Paragraph:

The Examiner has rejected claims 1-4 and 6-9 under 35 U.S.C. § 112, first paragraph, indicating that the specification fails to provide support for the phrase

"wherein said solution is effective as a single component solution." Applicant has amended the claims to conform with the terms utilized by those skilled in the art.

The claims have been amended to recite an aqueous solution that is effective as a single-part solution. A plain reading of the specification indicates that the solution is a single-part solution and not a multi-part solution. For example, paragraph **[0029]** provides a formulation for a single-part solution. The formulation contains all of the elements in a single solution and does not separate the individual elements into distinct solutions as commonly done in multi-part solutions.

Rejection under 35 U.S.C. § 112, Second Paragraph:

The Examiner has rejected claims 1-4 and 6-9 under 35 U.S.C. § 112, second paragraph, indicating that the claims are indefinite in failing to define a single component solution, considering that the claims use more than one component. Applicant has amended the claims thereby rendering this rejection moot.

The term "component" has been removed from the claim language to remove any ambiguity. Applicants utilized the term "component" to refer to a solution containing numerous elements, such as PHMB, chloride and saccharide. The claims now recite a "single-part solution," which as known by those skilled in the art, refers to a solution that is effective without the need to be combined with an additional solution, powder or tablet. Single-part solutions differ from multi-part solutions in that a multi-part solution must be mixed in order to be effective. As the term "component" has been removed from the claims it is respectfully requested that this rejection be reconsidered and withdrawn.

Rejection under 35 U.S.C. § 103(a) over Asgharian et al. in view of De Bruiju et al.:

The Examiner has rejected claims 1-4 and 6-9 under 35 U.S.C. § 103(a) as being unpatentable over Asgharian et al (U.S. 6,139,646) in view of De Bruiju et al (U.S. 6,162,393) for the resonse set forth on pages 3-5 of the office action of January 23, 2008. The January 23, 2008 office action indicates that Asgharian teaches a contact lens solution of a cationic polymeric preservative and a preservative enhancer of glycerin, sorbitol and a propylene glycol. The Examiner further states that the reference teaches a chloride concentration of less than 0.2 and the use of a buffer, sequestering agent, simple

saccharide. This rejection is urged as in error as the references fail to address all of the claimed limitations, the present invention provides suppressing results and the solution of Asgharian is inoperable as applied.

The Examiner relies on De Bruiju in combination with Asgharian solely for the teaching of decanedioc acid which was previously claimed in cancelled claim 5. As claim 5 is canceled this rejection is moot.

The references fail to teach all of the claimed limitations:

Asgharian relates to improving the stability of liquid enzyme solution containing both covalently modified trypsin and water using organic stabilizers. The stabilizers compete with water in the hydrogen bonding of the liquid enzyme solution to reduce the water-hydrogen bonding necessary for enzyme activity.

The instant invention relates to a effective single part aqueous solution with a specific combination and concentrations of a preservative enhancer, polyhexamethylene biguanide and chloride. The inventive solution is effectively preserved while reducing the amount of preservatives deposited on contact lenses.

Asgharian teaches a two-part solution where trypsin is an active ingredient in a first part that is combined with the second part. The second part contains sorbitol with a concentration of 1.2 weight/volume. There is no indication that the second solution would be effective as a contact lens solution by itself. Indeed, Asgharian teaches that the second part, the solution, need be combined with the first component containing trypsin to be effective. By contrast, the present invention claims a single-part solution that is effective as a contact lens solution without the need to combine with a second part. The omission of an element and the retention of its function is an indicia of non-obviousness. *In re Edge,* 359 F.2d 896, (CCPA 1966). The reference fails to teach a single-part solution and therefore, fails to teach or suggest all of the claimed limitations.

The instant invention provides surprising results:

Additionally, the instant invention demonstrates surprising results. The specific combination and concentrations of compounds claimed by the instant invention provides superior antimicrobial activity. Applicant kindly directs Examiner's attention to

paragraph **[0033]** of the specification. The antimicrobial activity of samples with no additive or chloride in excess of the claimed limitations show reduced activity, while the samples containing glycerin, sorbitol, mannitol, inositol and dextrose demonstrated increased activity. Paragraph **[0035]** of the specification demonstrates the reduced effectiveness of the solution as chloride concentration exceeds 0.2 weight percent. The Examples shown in the specification show surprising results as the specific combination and concentrations of compounds provides improvements over samples outside of the claimed range. Asgharian fails to note this result. As evidenced by Example 5D on column 15 of Asgharian, the solution containing mannitol and a chloride concentration above 0.2 weight percent. As discussed above, the high chloride concentration provides poor results when compared with the claimed invention.

The Examiner indicates the phrase "wherein the concentration of chloride is less than 0.2 percent by weight" encompasses the lack of chloride or chloride at zero concentration, which indicates the lack of criticality of chloride in the composition. However, as discussed above, it is when the chloride concentration is maintained at less than 0.2 percent by weight that the surprising results are shown. These surprising results provide a basis for the non-obviousness of the instant claims over the prior art.

As applied the solution of Asgharian is inoperable:

Combining Part I and Part II of the solutions taught by Asgharian result in an ineffective ophthalmic solution. As indicated in paragraph **[0003]** of the instant specification, ophthalmic solutions are available as over the counter products. Over the counter products are required to have a suitable shelf life and maintain effectiveness over the span of that shelf life. Asgharian teaches a multi-part solution that when combined has a short period of effectiveness. As indicated in Example 12, Table 6 and Table 7 of Asgharian, once the two parts are combine the stability of the active compounds is dramatically reduced over a short time. For Example, as shown in Table 6, after 1 day the solution looses over 10% activity and after 8 days the total remaining activity is drastically reduced to 65.6%. Combining Parts I and II of the solutions taught by Asgharian result in a solution having a short effective life. As such this combination is

not suitable as an effective single-part solution claimed by the instant invention. Therefore, it is requested that the rejection be reconsidered and withdrawn.

Applicant respectfully submits that Claims 1, 8 and 9 and all claims that depend therefrom are therefore in condition for allowance.

Applicant appreciates the opportunity to call the Examiner but believes that the forgoing remarks fully address the issues raised by the Examiner. On the other hand, the Examiner is invited to call the undersigned attorney if he has any matters to address that will facilitate allowance of the application.

In the event that Applicant has overlooked the need for an extension of time, additional extension of time, payment of fee, or additional payment of fee, Applicant hereby conditionally petitions therefore and authorizes that any charges be made to Deposit Account No.: 50-3010.

Respectfully submitted,

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